

REMARKS UNDER 37 CFR § 1.116

Formal Matters

Claims 1-2, 11, 13-30 and 44-45 are pending after entry of the amendments set forth herein.

Claims 2, 16-19, 21 and 23-30 are currently withdrawn from consideration.

Claims 1, 11, 13-15, 20, 22 and 44-45 were examined. Claims 1, 11, 13-15, 20, 22 and 44-45 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

The Office Action

Claim Objections

In the Official Action of June 11, 2008, claims 1 and 11 were objected to. Specifically with regard to claim 1, the Examiner indicated that the recitation of "said lower portion" in line 6 should be changed to --said lower spreader portion--. Applicants have made this change in the above amendment of claim 1.

The Examiner did not specifically identify any informality in claim 11, and Applicants have been unable to locate an informality. Accordingly, if the Examiner intends to maintain this objection of claim 11, the Examiner is respectfully requested to specifically identify where she determines the informality (ies) to be located in claim 11.

In view of the above amendment and remarks, the Examiner is respectfully requested to reconsider and withdraw the objection to claims 1 and 11 as being inappropriate.

Claim Rejected Under 35 U.S.C. Section 112, Second Paragraph

Claims 1, 11, 13-15, 20, 22-23 and 45 were rejected under 35 U.S.C. Section 112, second paragraph as being indefinite.

Regarding claims 1 and 11, the preambles have been amended to recite antecedent basis for “diaphragm” and “abdominal organs” and, with regard to claim 11, to further provide antecedent basis for “sternal area” and “abdomen”.

With regard to the Examiner’s question about “the same direction”, claim 11 has been recited to further define a free end of said depressor surface free end portion, a free end of a first of said pair of hooks, and a free end of a second of said pair of hooks. Further, claim 11 has been amended to recite that each of these three free ends extends in substantially the same direction.

In view of the above amendment and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 11, 13-15, 20, 22-23 and 45 under 35 U.S.C. Section 112, second paragraph, as being no longer inappropriate.

Claims Rejected Under 35 U.S.C. Section 102(b) (Nicholas et al.)

Claims 1 and 44 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Nicholas et al., U.S. Patent No. 5,967,974. The Examiner asserted that Nicholas et al. discloses an access system with upper and lower spreader portions 126, 112, the spreader portions being positioned relative to each other, the upper spreader portion comprising a hook 132 mounted to a retraction mechanism actuator via a swivel 128, wherein the lower portion comprises a flat depressor surface.

The Examiner asserted that the circular base 128b allows the mounted hook 132 to turn around upon it at gap 128c, qualifying it as a swivel (Figs. 8-9). Applicants respectfully traverse. The description of Figs. 8 and 9 of Nicholas et al. does not support the Examiner’s interpretation thereof. Rather, Nicholas et al. describes that the adjustment of the adjustable hook member 126 may be made by rotating the adjustment knob 128 so that post members 128c bias against the sidewalls of teeth 126b and urge adjustable hook member 126 in the desired direction due to the fixed nature of adjustment knob 128 with respect to frame member 110, see column 4, lines 51-57. Thus, the mechanism provided that includes the knob 128 functions like a rack and pinion mechanism, not a swivel.

To further clarify this distinction, claim 1 has been amended to recite that the recited retraction mechanism comprises a screw, and that the swivel is connected to said screw. Support for this amendment can be found, for example, at paragraph [0046] of the specification and throughout the specification and drawings. It is respectfully submitted that Nicholas et al. clearly fails to disclose the recited swivel connect to a screw as claimed.

In view of the above amendments and remarks, the Examiner is respectfully requested to

reconsider and withdraw the rejection of claims 1 and 44 under 35 U.S.C. Section 102(b) as being anticipated by Nicholas et al., U.S. Patent No. 5,967,974, as being clearly inappropriate.

Claims Rejected Under 35 U.S.C. Section 102(b) (Phillips)

Claims 11, 13, 20 and 45 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Phillips, U.S. Patent No. 4,865,019. The Examiner asserted that Phillips discloses an access system (Figs. 3-5) with upper and lower spreader portions 14, 13, the spreader portions being positioned relative to each other, the upper spreader portion 14 comprising a pair of hooks 48 for lifting the patient's sternal area, each of the pair of hooks having a free end portion independent of the other.

The Examiner asserted that Phillips discloses a lower spreader portion 30 comprising a depressor surface underlying the pair of hooks (when in closed un-retracted position with the two connector arms 15 and 16 being adjacent to each other). Applicants respectfully traverse. Initially, Applicants note that Phillips does not disclose "upper" and "lower" spreader portions 14 and 13, as 14 and 13 are side by side arm members of a sternal retractor as clearly shown in the top view of Fig. 3.

Further, Applicants respectfully submit that nowhere does Phillips disclose, show or suggest that sternal blade 30 would underlie fork-like structures 48. On the contrary, Phillips clearly discloses at column 3, lines 29-35 that the sternal blade is used to hold the left edge (38) apart from the right edge (37) before the rake retractors (46) are slipped onto the arm (14). Accordingly, there is never a configuration such as suggested by the Examiner. Furthermore, even if the retractor arms 14, 13 were to be closed all the way while having the rake retractors 26 mounted to 14, there is no disclosure to suggest that the sternal blade would then underlie the lower portions 48. Fig. 3 seems to suggest that this could not occur, since portions 15 and 16 would contact one another before portions 48 and 30. Still further, there is no disclosure by Phillips that the end of the blade 30 sits lower than the retractors 46, 48. Common sense would suggest otherwise, since in the unretracted configuration suggested by the Examiner, the retractor arms 14 and 13 are side by side, at even height, and retractor blade 30 is mounted over retractor arm 13, as shown in Fig. 3.

The Examiner asserted that the retractor blade 30 of Phillips has a free end portion that is extending downward, substantially in the same direction as the free end portions of hooks 48. Applicants respectfully traverse. To still further clarify this distinction, claim 11 has been amended above to recite that each of the end portion of the depressor surface and the free end portions of the pair of hooks has a

free end, and that each of these three free ends extends in substantially the same direction. Fig. 4 of Phillips clearly illustrates that the free end of the retractor blade extends to the right, while the free end (point) of the hook 48 extends to the left.

The Examiner asserted that the retractor blade of Phillips is capable of engaging the patient's diaphragm and abdominal organs to depress the abdomen. The Examiner did not refer to any of the disclosure of Phillips to support this conclusion. Applicants respectfully submit that the Examiner's conclusion is wholly unsupported by the disclosure of Phillips. Phillips discloses that the retractor blade 30 is a sternal retractor blade, see column 3, line 6 and the figures support this use, where the blade 30 is applied to an incision in the sternum and applies force against one side of the incision to retract that side of the sternum. As such the sternal retractor blade would be incapable of engaging the diaphragm or abdominal organs. .

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 11, 13, 20 and 45 under 35 U.S.C. Section 102(b) as being anticipated by Phillips, U.S. Patent No. 4,865,019, as being clearly inappropriate.

Claims Rejected Under 35 U.S.C. Section 102(b) (Shulman et al.)

Claims 11, 13 and 45 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Shulman et al., U.S. Patent No. 4,991,566. The Examiner asserted that Shulman et al. discloses an a device capable of providing a transabdominal access for a patient. Applicants respectfully traverse. Shulman et al. clearly discloses that the device 11 is for dilating and/or propping open a patient's jaw, see column 2, lines 18-20, and there does not appear to be any suggestion or disclosure by Shulman et al. that would support the Examiner's conclusion, nor has the Examiner identified any disclosure by Shulman et al. that supports the Examiner's conclusion.

The Examiner further asserted that Shulman et al. discloses a pair of hooks 21 capable of lifting the patient's sternal area.. Applicants strongly traverse. The dimension of the device 11 provided by Shulman et al. are designed to spread the jaws apart. It is respectfully submitted that the distance between the sternum and the back of the rib cage is far greater than the distance between a patient's jaws, and that therefore the mouth prop device of Shulman et al. would clearly be incapable of use for lifting the sternum.

It is further submitted that reference numeral 21 of Shulman et al. refers to a cushioning pad, not a hook, see column 8, and line 67.

Further, the free ends of the pads 21 extend in opposite directions, as they are mounted on shafts 22 that have free ends extending in opposite directions.

The Examiner indicated that “it has been held that the recitation that an element is ‘configured to’ perform a function is not a positive structural limitation in an apparatus claim but only requires the ability to so perform. In this regard, the Examiner cited a case from 1946 (*In re Hutchison*, 69USPQ 138) purportedly holding that the phrase “configured to” is not a positive structural limitation but requires only the ability to so perform. Applicants respectfully traverse. There have been many cases since 1946 where characterization of an element as “configured to” perform a function has been considered to be a structural limitation. For example, in *Helmsderfer et al. v. Bobrich Washroom Equipment, Inc. et al.* (2007 US Dist. LEXIS 60958), the court stated that the phrase “configured to engage the platform and secure the panel to the platform” defined the structure of a cap very well. This case was also affirmed at the CAFC, see 2008 US App. LEXIS 11818 (Fed. Cir., June 4, 2008). In *National Presto Industries, Inc. v. West Bend Company* (28 USPQ2d (BNA) 1049), the court found that a claim reciting “a retention chamber which is configured for reception within the retention compartment” was not obvious in view of Japanese publications asserted thereagainst. The court stated that in order for claim 1 to have been obvious, the method described in the Japanese invention for coupling separate receptacles would have to suggest to a person skilled in the art the method of forcing the blade into the potato by insertion of the receptacles one within the other. This case was upheld by the CAFC, see 76 F.3d 1185 (1996). In *Advanced Cardiovascular Systems, Inc. and Guidant Sales Corporation v. Scimed Life Systems, Inc. and Boston Scientific Corporation* (216 F.3d 1329), the court considered the characterization of connection elements as “configured to interconnect only said cylindrical elements that are adjacent to each other” as a structural limitation. It is respectfully submitted that the device of Shulman et al. is not configured to be used to lift the sternal area and depress the diaphragm and abdominal organs and it is not physically capable of doing so due, at least in part, to its small size. Shulman et al. explicitly discloses that the device 11 is used to prop open the mouth of a patient.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 11, 13 and 45 under 35 U.S.C. Section 102(b) as being anticipated by Shulman et al., U.S. Patent No. 4,991,566, as being clearly inappropriate.

Claims Rejected Under 35 U.S.C. Section 102(b) (Santilli et al.)

Claims 11, 13, 20 and 45 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Santilli et al., U.S. Patent No. 6,099,468. The Examiner asserted that Santilli et al. disclose an upper spreader portion 46 and a lower spreader portion 22 being positioned relative to each other to produce a substernal space. Applicants respectfully traverse. Applicants respectfully submit that Santilli et al. does not disclose “upper” and “lower” spreader portions 46 and 22, as 46 is a rod mounted to retractor arm 20 and retractor arms 20, 22 are side by side arm members of a sternal retractor as clearly shown in Fig. 1.

The Examiner further asserted that retractor blades 78,80 are capable of lifting the patient’s sternal area. Applicants respectfully traverse. Santilli et al. clearly discloses that the grips 12, 14 of the sternal retractor are used to retract the sternum, see column 4, lines 52-54. The retractors blades 78, 80, 82 are used to expose the heart, by retracting soft tissues from the area, see column 4, lines 60-62. Retractors 78-80-82 are not used to retract the sternum and are not capable of doing so given the configuration disclosed by Santilli et al.

The Examiner referred to a “lower spreader portion 22” comprising “depressor surfaces 14 and 82” and indicated that these surfaces underlie the pair of hooks 78 and 80 when portion 22. There is no disclosure in Santilli et al. to support the Examiner’s conclusion, which is purely speculative. On the contrary, Santilli et al. discloses that grips 12, 14 are immediately adjacent one another when arm 22 is moved toward arm 20, see column 4, lines 47-49. It is only after the grips have been moved apart that the brackets 36 are attached to the bars 32, see column 4, lines 55-56. Accordingly, it is respectfully submitted that the Examiner’s conclusion is fictional and wholly unsupported by the disclosure of Santilli et al.

The Examiner further asserted that the free end of 14 is extending in substantially the same direction as the free ends of hooks 78 and 80. Applicants respectfully submit that Fig. 1 clearly shows that the free end of 14 is directed toward the right side of the patient (when device 10 is in place for its intended function), hook 80 is pointing anteriorly, and hook 78 is pointing toward the left side of the patient, and somewhat posteriorly. Clearly these are all very distinct directions.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 11, 13m 20 and 45 under 35 U.S.C. Section 102(b) as being anticipated by Santilli et al., U.S. Patent No. 6,099,468, as being clearly inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Nicholas et al. in view of Phillips)

Claims 11, 13-15 and 22 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Nicholas et al., U.S. Patent No. 5,967,974, in view of Phillips, U.S. Patent No. 4,865,019. The Examiner admitted that the system of Nicholas does not include a pair of hooks on the upper section. The Examiner asserted that the “depressor surface 112a” is underlying hook 132, as best shown in Fig. 2 when 112 and 132 are adjacent one another. Applicants strongly traverse. It is respectfully submitted that Fig. 2 of Nicholas et al. shows the opposite of what the Examiner has indicated. That is, Fig. 2 clearly shows that 112 is not underlying 132, but is shown to the right of it. No portion of 112 underlies 132 in Fig. 2.

The Examiner further asserted that “depressor surface 112a has a free end portion which is extending downward, substantially the same direction as the free end portion of hook 132”. Again Applicants respectfully traverse. First, Applicants note that 112a is not a surface but a slotted opening, see column 3, line 33. Second, Fig. 2 clearly shows the Free end of 112 pointing downward and slightly to the right, while the free end of 132 points mainly to the left and only slightly downward. It is respectfully submitted therefore, that the free ends of 112 and 132 clearly point in distinctly different directions.

The Examiner asserted that it would have been obvious to provide the upper spreader portion of Nicholas et al. with a pair of hooks, as taught by Phillips, to spread the forces evenly along the incision. Applicants respectfully traverse. It is respectfully submitted that the broad surface of the component 112 already spreads the forces more efficiently than the two sharpened tips of the hooks 48 of Phillips and that therefore no one of ordinary skill in the art would have made the modification suggested by the Examiner.

However, even if it would have been obvious to combine the references as suggested by the Examiner, which, for at least the above reasons, Applicants submit that it would not have been obvious, the resulting combination would still not meet all of the recitations of the rejected claims. It is respectfully submitted that neither Nicholas et al. nor Phillips discloses, teaches or suggests a depressor surface that underlies said pair of hooks as claimed, and that a free end of said depressor surface extending substantially in the same direction as the free ends of the pair of hooks.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 11, 13-15 and 22 under 35 U.S.C. Section 103(a) as being unpatentable over Nicholas et al., U.S. Patent No. 5,967,974, in view of Phillips, U.S. Patent No.

4,865,019, as being inappropriate.

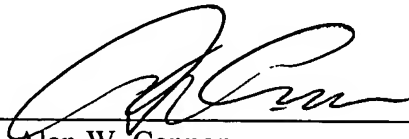
Conclusion

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-036.

Respectfully submitted,
LAW OFFICE OF ALAN W. CANNON

Date: 8/8/08

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